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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,086	12/05/2003	Fred H. Burbank	R0367-02501	8823

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Edward J. Lynch
DUANE MORRIS LLP
One Market
Spear Tower, Suite 2000
San Francisco, CA 94105

EXAMINER

SMITH, FANGEMONIQUE A

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/729,086

Applicant(s)

BURBANK ET AL.

Examiner

Fangemonique Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-54 and 66-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-48, 51-54, 66-70, 73-76 is/are rejected.
- 7) ☒ Claim(s) 49, 50, 71 and 72 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed June 22, 2006. The Examiner acknowledges the cancellation of claims 1-24, 55-65 and the amendment of claim 37. Claims 25-54 and 66-76 are pending in the application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 25-39, 44-48, 51, 66-70 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al. (U.S. Patent Number 5,683,384) in view of Ritchart et al. (U.S. Patent Number 5,810,806).

In regard to claims 25-36, Gough et al. disclose the features of the Applicant's invention as described in previous office action including a multiple antenna ablation apparatus, which upon use applies a method for accessing and anchoring tissue which corresponds to a lesion site within the body of a patient which includes locating the lesion; accessing tissue with an anchoring device having an elongated shaft (18), a distal end (14), a proximal end, a longitudinal axis, a radially extending anchoring element (16) and a tissue cutting member located at the distal end of the shaft; extending at least one anchoring element from the shaft into the tissue corresponding to the lesion site and securing the distal end of the device to the tissue

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corresponding to the lesion site (col. 7, lines 3-67; col. 8, lines 1-65). The method disclosed by Gough et al. further discloses securing the tissue of interest by radially extending the anchor element and emitting RF energy during the deployment of the element. The device has an RF powered electrode as the tissue cutting members as well as an arcuate shaped wire spaced distally from a distal extremity of the distal end of the cannula (col. 6, lines 35-67; col. 7; col. 8, lines 1-54). The Gough et al. apparatus also has a controller coupled to an ultrasound imaging device (col. 9, lines 41-67). Although Gough et al. discloses features of Applicants invention, Gough et al. do not disclose the device detecting radiation from a radioactive material within the lesion site. Gough et al. also do not disclose the use of a gamma camera to determine the approximate positioning of the target tissue. Ritchart et al. disclose a method and device for collection of soft tissue. The device disclosed by Ritchart et al. includes a tissue sampling probe and a gamma camera (col. 3, lines 1-10). The Ritchart et al. device further includes a slidable radiation detector for detecting radioactive material while locating a lesion in an area of soft tissue (col. 11, lines 34-67; col. 12, lines 1-24). It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a multiple antenna ablation apparatus, similar to that disclosed by Gough et al., to include a gamma camera, and a radiation detector, similar to that disclosed by Ritchart et al., to include additional mechanisms to assist with localizing a tissue site.

In regard to claims 37-39, Gough et al. disclose the features of the Applicant's invention as described above including a node accessing and anchoring device (10) comprising an elongated shaft (18) having an inner lumen, a distal end (14), a proximal end, a longitudinal axis, a radially

extending anchoring element (16) and a tissue cutting member located at the distal end of the shaft as shown in Fig. 3.

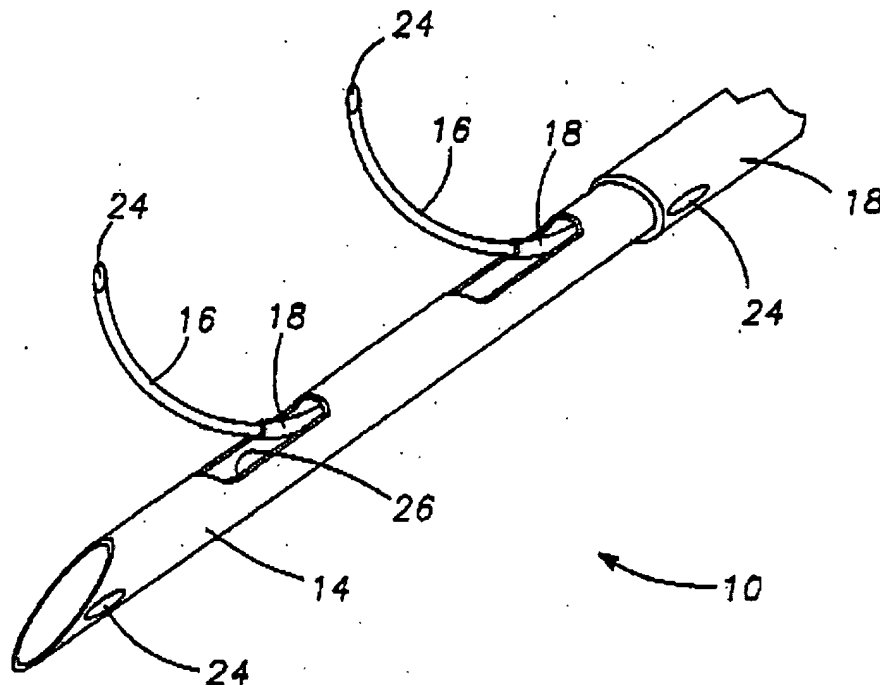


FIG. -3

The Gough et al. device includes at least one anchoring element having a retracted configuration and an extended configuration (col.7; col. 8, lines 1-54). Although Gough et al. disclose having sensors other than thermal sensors as a detector located within the inner lumen of the elongated shaft, Gough et al. do not disclose the device having a radiation detector to detect radioactive material from the lesion site. Ritchart et al. disclose a device for collection of soft tissue. The

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device disclosed by Ritchart et al. includes a tissue sampling probe and a gamma camera (col. 3, lines 1-10). The Ritchart et al. device further includes a slidable radiation detector for detecting radioactive material while locating a lesion in an area of soft tissue (col. 11, lines 34-67; col. 12, lines 1-24). It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a multiple antenna ablation apparatus, similar to that disclosed by Gough et al., to include a gamma camera, and a radiation detector, similar to that disclosed by Ritchart et al., to include additional mechanisms to assist with localizing a tissue site.

In regard to claims 44-48, 51, 66-70 and 73, Gough et al. disclose the features of the Applicant's invention as described above including a node accessing and anchoring device (10) comprising an elongated shaft (18) having an inner lumen, a distal end (14), a proximal end, a longitudinal axis, a radially extending anchoring element (16) and a tissue cutting member located at the distal end of the shaft. Gough et al. disclose having an electrical lead coupled to at least one radially extending wire and a second electrical lead coupled to the patient providing an arrangement which allows RF energy to be applied to at least one anchoring element during deployment of the anchoring device for ablating and penetrating tissue (col. 5, lines 34-67; col. 6, col. 7; col. 8, lines 1-54; Figs. 9 & 10). The Gough et al. device includes at least one anchoring element having a retracted configuration and an extended configuration (col. 7; col. 8, lines 1-54). Although Gough et al. disclose having retracted and deployed configurations, Gough et al. do not disclose a deployment actuator located proximal of the distal end of the elongate shaft as part of the device. Ritchart et al. disclose a device for collection of soft tissue. The device disclosed by Ritchart et al. includes a tissue sampling probe and a gamma camera

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(col. 3, lines 1-10). The Ritchart et al. device further includes a deployment actuator (30) disposed proximal of the distal end of the elongate shaft (col. 7, lines 1-42). It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a multiple antenna ablation apparatus, similar to that disclosed by Gough et al., to include an actuator, similar to that disclosed by Ritchart et al., to include a manual control mechanism to assist with accessing and anchoring the medical tool to the desired tissue site.

4. Claims 40-43, 52-54 and 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al. (U.S. Patent Number 5,683,384) in view of Ritchart et al. (U.S. Patent Number 5,810,806) and in further view of Mulier et al. (U.S. Patent Number 5,431,649)

In regard to claims 40-43, 52-54 and 74-76, the combined references of Gough et al. and Ritchart et al. disclose the features of the Applicant's invention as described above. The combined references do not disclose the anchoring element forming a curved, helical structure as it extends. Mulier et al. disclose a helical coil electrode, which extends through at least 540 degrees. The helical coil electrode is anchored into heart tissue. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a multiple antenna ablation apparatus, similar to the apparatus disclosed by the combined Gough et al. and Ritchart et al. references, to incorporate a helical coil electrode which extends through at least 540 degrees, similar to that disclosed by Mulier et al., to provide a more stable connection between the device and the tissue.

Response to Arguments

5. Applicant argues Gough et al. (U.S. patent Number 5,683,384) does not disclose the use of radiation detectors. Examiner submits Gough et al. suggests different sensors used other than temperature sensors, however Examiner agrees that the reference does not suggest the use of radiation detectors. Applicant's arguments, see Response to Office Action, filed June 22, 2006, with respect to the rejection(s) of claim(s) 37-39 under 35 USC 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the combined references of Gough et al. (U.S. Patent Number 5,683,384) and Ritchart et al. (U.S. Patent Number 5,810,806).

6. Applicant indicated claims 25-36 were cancelled. However, there was no indication of these claims being cancelled other than in the written response. Since the claims were not identified as canceled, Examiner addressed claims in this office action. If Applicant intends to cancel claims 25-36, the status identifier for each claim needs to reflect a cancelled status.

Allowable Subject Matter

7. Claims 49, 50, 71 and 72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Terminal Disclaimer

8. The terminal disclaimer filed on June 22, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of the full

statutory term of U.S. Patent Number 6,679,851 has been reviewed and is accepted. The terminal disclaimer has been recorded.

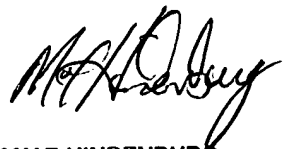
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS


MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700